

This is an official Oklahoma Health Alert Network Health Update

October 10, 2017 OKHAN-258-2017-10-10-UPD-N

Updated Zika and other Travel-associated Arboviral Diseases Screening Guidance

Summary

This HAN Advisory serves to inform healthcare providers across the state that new Zika screening and evaluation guidance has been implemented by the Oklahoma State Department of Health (OSDH) to reflect changes in guidance published by the Centers for Disease Control and Prevention (CDC).^{1,2} For this reason, the OSDH Acute Disease Service (ADS) has updated our Zika clinician packet and laboratory guidance documents. Clinicians should use the updated forms during patient evaluation to determine if the clinical and travel criteria are met to access diagnostic testing for Zika virus infection.

Updated Testing Recommendations

Symptomatic Patients with Zika Exposure

It is still recommended to test symptomatic patients with at least two Zika-compatible symptoms (fever, rash, arthralgia, conjunctivitis) who report travel to or sexual contact with a person who resides/visited a Zika outbreak-affected country.

Asymptomatic Pregnant Women

New changes have been implemented for asymptomatic pregnant women. CDC has established two risk levels for asymptomatic, pregnant females: (1) Pregnant women with ongoing exposure, and (2) those without ongoing exposure. Ongoing exposure is defined as those who have had foreign residence in a Zika-affected country during pregnancy or the eight weeks prior to conception, as well as those patients who report frequent (at least monthly) travel to a Zika-affected region.

1. Asymptomatic, Pregnant Women With Ongoing Exposure

It has now been established that previous residence in a Zika-affected country or frequent travel to a Zika-affected region places a pregnant women and her fetus at higher risk of both infection and adverse outcomes.

It is recommended to continue to test women in this category for Zika virus infection. It is important to understand there has been a change in the frequency and testing type. The Zika IgM test has proven to be unreliable for asymptomatic, pregnant women as CDC studies have now shown that IgM levels can actually remain elevated well beyond 200 days post-exposure making it impossible to determine if positive IgM results reflects exposure that occurred prior to conception or is actually reflective of recent travel or sexual exposure. This makes follow-up difficult and confusing for both clinicians and patients. For this reason, CDC is now recommending asymptomatic, pregnant women with ongoing Zika exposure to be only tested by PCR three times during pregnancy. Testing should occur at initial prenatal visit and then two additional times, preferably once per trimester.

2. Asymptomatic, Pregnant Women Without Ongoing Exposure

CDC's new guidance states that Zika testing for this category of women is no longer recommended for the majority of states. Oklahoma is not a border or high risk state with documented local mosquito transmission of Zika virus. Furthermore, both state and national data support the notion that the risk of Zika virus infection in pregnant women who only travel out of the US for vacation or short stays are at a low risk of developing Zika virus disease, thus low risk to the fetus acquiring infection.

Asymptomatic, pregnant females comprise approximately 75% of consultations and testing requests done by the Oklahoma State Department of Health. Since February 2016, OSDH has tested 544 asymptomatic, pregnant females with either travel to Zika-affected region or reported sexual exposure with a partner who traveled to high risk area; one (0.18%) tested positive for Zika virus infection.

Given the strong state and national data supporting the low risk of Zika virus in this group, the OSDH will no longer be testing women in this category or their sexual partners. Women (or partners) who still desire testing outside of CDC guidelines may elect to pursue testing through a commercial reference laboratory.

Infant and Placental Testing

The OSDH will continue to evaluate and test infants who have suspected or confirmed microcephaly or other neurologic birth defects (diagnosed prenatally or at birth) whose mother was potentially exposed to Zika virus, as well as infants born to mothers with laboratory evidence of Zika virus infection during pregnancy.

Summary

If the completed screening process indicates the patient is at risk for Zika virus infection, notify the ADS epidemiologist-on-call at (405) 271-4060 for consultation, to confirm all criteria for testing are met, and to coordinate specimen collection and submission. Once the patient has been approved for testing, clinicians should follow the attached specimen collection guidance to submit the required specimen(s) to the OSDH Public Health Laboratory (PHL). The epidemiologist-on-call will work with clinicians to coordinate specimen transport to the PHL. Guidance related to appropriate specimen collection, handling, and shipping can be found in the attached "Laboratory Testing Guidance" document.

Please note CDC is currently offering a free continuing education (CE) activity discussing recent updates regarding U.S. pregnant women and infants with recent Zika virus exposure. Interested clinicians can register at the following link: https://www.cdc.gov/mmwr/cme/medscape_cme.html

Healthcare providers can contact the ADS epidemiologist-on-call at (405) 271-4060 for questions or clarification regarding this guidance or Zika Virus testing.

- 1. Updated Guidance for US Laboratories Testing for Zika Virus Infection, Centers for Disease Control and Prevention, July 24, 2017, accessed at https://www.cdc.gov/zika/pdfs/laboratory-guidance-zika.pdf
- 2. The Updated Interim Guidance for Healthcare Providers Caring for Pregnant Women with Possible Zika Virus Exposure United States, July 2017:

https://www.cdc.gov/mmwr/volumes/66/wr/mm6629e1.htm?s_cid=mm6629e1_w

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Categories of Health Alert messages

Health Alert highest level of notification that the Oklahoma State Department of Health will send out. This usually refers to an immediate threat to the OSDH community and requires immediate action.

Health Advisory advises medical providers of a condition in the area. These are usually not medical emergencies. These may not require immediate action. **Health Update** provides updates on previous alerts or advisories. These are unlikely to require immediate action.

This advisory has been distributed to Primary Care and Obstetrics & Gynecology Physicians, Emergency Departments,
Infection Preventionists, Advance Practice Nurses, and State and Local Health Officials ##

You have received this message based upon the information contained within our emergency notification database. If you have a different or additional e-mail or fax address that you would like us to use please contact the OSDH Acute Disease Service at (405) 271-4060.

ZIKA AND OTHER TRAVEL-ASSOCIATED ARBOVIRAL DISEASES SCREENING AND EVALUATION GUIDANCE

ACTIONS REQUESTED OF CLINICIANS: If patient meets one of the criteria below, please:

- 1. Fill out the screening form.
- 2. Fax it to Oklahoma State Department of Health (OSDH), Acute Disease Service (ADS) at (405) 271-6680.
- 3. Call the epidemiologist-on-call at (405) 271-4060 to consult and obtain the required pre-approval for testing.
- 4. If patient is approved for testing, <u>complete the attached OSDH Public Health Lab requisition form for each specimen</u>. This form is <u>required</u> to be submitted with each specimen collected for testing at the Public Health Lab.

If a patient meeting the criteria below is seen during non-business hours, specimens can be collected and held refrigerated until the next business day when an OSDH ADS epidemiologist is available for consultation and submission approval. If the patient is part of a suspected outbreak, or suspected local transmission event, please contact the ADS epi-on-call immediately at (405) 271-4060 (available 24/7/365).

Symptomatic Individuals with Travel History or Concern for Sexual Transmission:

◆ Two or more of the following symptoms: Acute fever, rash, arthralgia, conjunctivitis;

AND

◆ Travel to a Zika-affected area within 2 weeks prior to symptom onset. Countries or areas within the continental U.S. at risk for Zika transmission can be determined by accessing the following website: http://wwwnc.cdc.gov/travel/page/zika-travel-information;

OR

• Concern for sexual transmission: Reports unprotected sex with partner(s) who traveled to a Zika-affected area. Specimen must be collected within 12 weeks after partner's departure from a Zika-affected country in order to be eligible for testing;

AND

♦ Ability to collect urine and serum specimens within 12 weeks of symptom onset. Additional specimens may be requested during consultation with an ADS epidemiologist.

Asymptomatic, Pregnant Women:

- ◆ Those with ONGOING* possible Zika exposure:
 - Should be tested three times during pregnancy.
 - At initial prenatal visit and then two more times, preferably each trimester.
 - Collect urine and serum samples for Zika virus RT-PCR testing.
- ◆ Those without ONGOING* possible Zika exposure:
 - **Testing is no longer recommended** (i.e., vacation travel, unprotected sexual exposure following vacation travel).

*Ongoing possible exposure to Zika virus includes frequent (at least monthly) travel to a Zika-affected area or frequent (at least monthly) unprotected sex with a partner who either resides in or frequently travels to a Zika-affected area. Travelers with short stays overseas (e.g., vacations, short mission trips) regardless of pregnancy status are no longer eligible for testing at the Oklahoma State Department of Health. Patients interested in Zika testing that don't qualify for testing at OSDH can access testing through major reference laboratories at the patient's expense.

Infant and Placental Testing:

- Infants who have suspected or confirmed microcephaly or other neurologic abnormality (diagnosed prenatally or at birth) and mother was potentially exposed to Zika virus.
- ♦ Infants who were born to mother with laboratory evidence of Zika virus infection during pregnancy.





Zika and Other Travel-Associated Arboviral Diseases Laboratory Testing Guidance

Zika virus testing is performed by the Oklahoma State Department of Health (OSDH) Public Health Laboratory (PHL). However, prior to specimen collection/submission, an epidemiologist from the OSDH Acute Disease Service (ADS) must gather pertinent clinical signs and symptoms, travel, and other epidemiologic information from the clinician to determine if a patient meets the required criteria for Zika virus testing as indicated by the Centers for Disease Control and Prevention (CDC). All specimens must be approved by the ADS prior to shipping to the OSDH PHL for testing.

The OSDH PHL is a CDC-designated laboratory that performs Zika virus testing by Emergency Use Authorization using the CDC Zika IgM Antibody Capture (MAC) ELISA and the CDC Trioplex Real-time RT-PCR Assay. Specimens may be referred by the OSDH PHL to the CDC or other laboratories for additional testing, as indicated.

For questions concerning Zika testing criteria, contact the OSDH ADS epidemiologist-on-call at (405) 271-4060.

For questions regarding specimen collection, storage, transport, and lab requisition forms, contact the **OSDH PHL Client Services at (405) 271-5070**.

Please, note that an **OSDH PHL Test Requisition Form** <u>must</u> be submitted with <u>each</u> specimen.

If the form is not completed appropriately, or is not received, testing may be canceled or significantly delayed.

• Urine <u>and</u> serum are the preferred specimen types and are required for each individual approved for testing. Additional specimens may be recommended during consultation with an ADS epidemiologist.

Specimen Collection, Storage, and Shipping:

- o **Whole blood** in serum separator tube (SST) (a.k.a., tiger-top tube)
 - Following collection, gently invert SST no more than 8 times then allow blood to clot in upright position for at least 30 mins and no more than 60 mins then centrifuge at 3000 rpm for 10 mins.
 - ≥ 2.0 mL (minimum) required; collect additional tubes to meet volume requirements, as needed.
 - Store refrigerated (2-8 °C) and ship using ice packs.
 - If transit time will be > 7 days post-collection, pour serum into a sterile, leak-proof, screw-cap tube and store/ship frozen (-20°C or colder).
- Urine in sterile container with sterile screw-cap container
 - Following collection, transfer urine to a sterile screw-cap container. To prevent leakage during shipping, secure parafilm around container cap. Do not ship urine cups.
 - ≥ 1.0 mL (minimum) required; must be submitted together with a patient-matched serum specimen.
 - Store refrigerated (2-8 °C) and ship using ice packs; prefer specimen frozen (-20°C or colder), then shipped on dry ice, if possible.
- o **CSF and amniotic fluid** in sterile screw-cap container
 - ≥ 1.0 mL (minimum) required; must be submitted together with a patient-matched serum specimen.
 - Store refrigerated (2-8 °C) and ship using ice packs; prefer specimen frozen (-20°C or colder), then shipped on dry ice, if possible.
- Other specimens types
 - For submission of other specimen types, such as placenta tissue or umbilical cord, coordinate with the OSDH ADS epidemiologist-on-call at (405) 271-4060.

Phone: (405) 271-4060 Fax: (405) 271-6680 Website: http://ads.health.ok.gov

Completing the Test Requisition Form

- o An OSDH PHL Test Requisition Form must be completed and submitted with each specimen type.
- o The OSDH *PHL Test Requisition Form* can be downloaded/electronically completed at the OSDH PHL website ("Forms") or a hard copy can be provided by the OSDH ADS epidemiologist-on-call.
 - Include patient's name or unique patient identifier (e.g., MR#), DOB, sex, specimen type, date of specimen collection, name and address of submitter, and test requested.
 - Indicate specimen source; a separate test requisition form is required for each specimen type, e.g., if submitting a serum and urine specimen on the same patient, then two test requisition forms will be required.
 - Under the Virology section of the form, mark 'Zika virus, IgM antibodies and/or Zika virus, chikungunya virus, dengue virus, PCR'.

Shipping to the OSDH PHL

o Ship to the OSDH PHL Monday through Thursday using the following address:

OSDH Public Health Laboratory 1000 NE 10th Street Oklahoma City, OK 73117-1299

- o For specimens that cannot be shipped immediately, store according to specimen storage guidelines above.
- o Specimens must be packaged and shipped in accordance with Category B agent guidelines.
- o Courier service to the OSDH PHL may be available through your local hospital; contact the PHL Client Services.

Cautionary Note Regarding Alternative Commercial Testing

Currently, several commercial laboratories in the US offer Zika virus testing using real-time RT-PCR. However, these laboratories do not provide Zika IgM ELISA testing with PRNT confirmation, and have no routine process to forward specimens to another laboratory when test results are negative. Therefore, if requesting Zika rRT-PCR testing from a commercial laboratory, providers should request the draw site/laboratory to retain an aliquot of the serum for Zika IgM testing if the rRT-PCR testing is negative. Whole blood should be collected and processed per guidelines of the commercial testing laboratory but serum from an additional serum separator tube should be transferred to a polypropylene tube and stored refrigerated (2-8°C) until it is known if additional IgM testing is indicated. If a serum aliquot cannot be stored or is not available, but further testing is indicated, a new blood sample should be collected.

ZIKA AND OTHER TRAVEL-ASSOCIATED ARBOVIRAL DISEASES SCREENING FORM

Please complete all sections of the form, fax to the Acute Disease Service (ADS), F:(405) 271-6680, and then call the ADS epidemiologist-on-call at (405) 271-4060 prior to specimen collection and submission. Please complete all fields.

Patient Information							
Last Name:		First Name:			MI:		
Date of Birth://_	Sex: □ Ma	le 🗆 Female					
Address:		City:	County:	State: _	Zip:		
Primary contact number:		Secor	dary contact number:				
			iian/Pacific Islander □ Asian				
□ Unknown □ C	Other						
Ethnicity: ☐ Hispanic ☐ Non			uage:	□ Inter	preter needed		
Healthcare Provider Information	tion						
Name of Reporting Person:							
Ordering Physician:							
Work Phone:	Fax Number:		Organization:				
Address:							
City:		State:	Zip Co	ode:			
Symptom Information							
Did patient have two or more	e of the symptoms below	v? □ Yes □ No	(If yes, complete symptom i	nformatio	n below. If no, g		
to next question.)							
Is the patient pregna	ınt? □ Yes □ No (If yes	s, go to next que	stion. If no, testing not ind	icated.)			
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		•	area? (If no, testing not ind		•		
exposure assessmen				,	,,,		
	,						
Symptom Onset date:/_	/						
Fever (subjective OR measure		known <i>If</i>	yes, max temp:				
Rash	□ Yes □ No □ Unl	-	ash description: Petechial		r □ Vesicular		
Conjunctivitis	□ Yes □ No □ Unl				. = 100.00.0.		
Arthralgia	□ Yes □ No □ Unl						
Was the patient hospitalized	? □ Yes □ No □ Unkno	wn					
Hospital name:			/ / Discharg	e Date:	/ /		
Exposure Assessment							
If symptomatic:							
Within 14 days before sympt	om onset did the natier	nt travel in an ar	ea in which 7ika virus is nrese	nt?			
\square Yes \square No (<i>If yes</i> , please list	•		•				
	•	•	kual partner following their re	turn from	a 7ika-affected		
			etails on the following page. I				
country: 🗀 resi	_ No (ij yes, piease list p	artifer 3 traveru	ctails on the following page. I	i iio, testii	ig not indicated.)		
If asymptomatic and pregnar	nt·						
Did the patient live in a foreig		ooks prior to con	contion or anytimo during pro	vanancy2 F	□ Voc □ No		
If yes, please list country of fo		•	conton anythine during pre	Silalicy: L	_ 1€3		
Country:	tos of residence:	:s of residence.	/ /				
Country: Da	tes of residefice:	<i>JJ</i>					
Does the pregnant patient re	nort frequent (at least n	nonthly) travel to	n a 7ika outhreak-affected re	gion durin	g nregnancy?		
Does the pregnant patient it	port in equenit (at icast ii	nondiny, davel t	o a zina batorcan arrecteu le	Pion anim	p bi chimich:		



ZIKA AND OTHER TRAVEL-ASSOCIATED ARBOVIRAL DISEASES SCREENING FORM

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							otected sexual exposure to a partner who has contin	— ued to		
			try during client's				oteotea sexual exposure to a partner who has contin	aca to		
							l exposure during pregnancy?			
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Ехро	sure A	ssessment (Continued)							
Refe	r to CD	C Zika Trave	lers Advisory page	for list	of countries: ht	ttp:	//wwwnc.cdc.gov/travel/page/zika-travel-informatio	<u>n</u>		
	If v	res list which	h countries and re	gions/a	reas/cities visit	ed	and dates of travel:			
		Country								
	-,	Date Arrive	ed in Country:				Date Departed Country://			
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*		f live birth, w	hat was date of de	elivery a	and facility of de	live	nancy: □ Live birth □ Fetal loss □ Elective terminatiry: eturning from a Zika affected country or region?	on 		
	□ Yes [•	ome pregnant with	ш аррі	ox. 2 weeks are	21.10	eturning from a zika affected country of region:			
*	Has the	e patient eve	er been vaccinated	for Yel	low Fever or Ja	pan	ese encephalitis? ☐ Yes ☐ No ☐ Unknown			
		e patient pre □ No □ Unk			•		ngunya, Yellow Fever, or West Nile virus? nd year:			
*		e patient bee Chikungunya			gies for the curr		illness? ☐ Yes ☐ No ☐ Unknown te of test// Result:			
		engue	Lab name:			Da	te of test/ Result:			
		☐ West Nile Virus Lab name:				Date of test// Result:				
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FOR	INTERI	VAL USE ON	LY:							
	☐ Syn	nptomatic	☐ Pregnant	☐ Ong	going Exposure		☐ Specimen < 14 days from symptom onset or exposu	re		
	-	mptomatic	☐ Not Pregnant	_	Ongoing		☐ Specimen ≥ 14 days and < 12 weeks from symptom			
	•		_	Exposi			or exposure			





Oklahoma State Department of Health Public Health Laboratory

1000 N.E. 10th Street, Oklahoma City, OK 73117-1299 Tel: (405)271-5070; Fax: (405)271-4850

Email: PublicHealthLab@health.ok.gov
Test Directory: http://phl.health.ok.gov

Laboratory Director: S. Terence Dunn, PhD

CLIA #: 37D0656594

Please, PRINT; *indicates required fields

Patient Information									
Name (last, first)*,,			Ini	tial	DOB*_	/	_/		
Address		City			State _	Zip			
Sex:* □ M □ F Ethnicity: □ Hispanic/Latino	☐ Non-His	oanic/No	n-Latino		Unknown				
Race: (mark all applicable)	an 🗖				lian/ Alaska	a Native			
Submitter Information									
Practitioner Name (last, first)*									
Facility Name*	_ Phone # ()	-	Fax # ()	-			
Address*		City* _			_ State	Zip*			
Clinical Information									
Diagnosis				Onset (m	ım-dd-yyy)	/ _	/		
Antibiotics (list and start dates)									
Specimen Information									
Collection Date (<i>mm-dd-yyy</i>)* / / Time (<i>hour:</i>	minute)	AN	1 / PM	Ву					
□ Blood □ Serum □ Urine □ Stool □ CSF □ Pleural fluid □ Sputum, expect. □ Sputum, induced □ Bronchial brush □ E □ Nasopharynx □ Nasal □ Throat □ Eye □ Rectum/anus □ Tissue (specify): □ Cultured isolate (specify suspect agent): □ Other (specify):	Bronchial wasl	h □ Bro I Cervix Lesion <i>(s_l</i>	nchoalve		ge 🗖 Trac	heal aspi	rate		
Test Request (mark <u>one</u> only)									
Bacterial isolate, identification/serotyping/confirmation Variable specimen according to source (contact lab) Bacteria, non-enteric, isolation and identification Variable specimen according to source (contact lab; requires pre-approval) Enteric pathogens, isolation and identification Feces, 2 g or 5-10 mL in Cary Blair or GN Broth (STEC only) Bordetella Nasopharynx, 1 or 2 swabs; Isolate, confirm visible growth Chlamydia/Gonorrhea Urine, first 20-60 mL of void − transfer to UPT tube Group B streptococcus Vaginal/anal swab in LIM broth (combined vaginal/anal collection preferred) Syphilis, RPR w/ reflex to TP-PA Serum in SST, 2 mL Syphilis, RPR and TP-PA Serum in SST, 2 mL; (CHDs only, requires pre-approval by DIS) Bacteria, environmental (contact lab)	 Virology □ Hepatitis B surface antigen (HBsAg) Serum, 2 mL (approved submitters only) □ HIV-1/2 antigen/antibodies Serum in SST, 2 mL (approved submitters only) □ Human papillomavirus, high risk Residual ThinPrep, 1 mL □ Influenza virus A and B Nasopharyngeal (preferred), nasal or throat swabs, 1 or 2 in VTM □ Rubella antibodies Serum in SST, 1 mL (female CHD patients only) □ Virus isolation and/or identification Throat, nasopharynx, rectum, eye, lesion, 1 swab in VTM; Blood, 5 mL heparin; Feces, 2 g or 5-10 mL; CSF, 1 mL; Eye scrapings in VTM; Urine, 20 mL (first morning void); Isolate; Other (contact lab) □ West Nile virus/St. Louis encephalitis virus, IgM antibodies Serum in SST, 2 mL; CSF, 1 mL (CSF must be accompanied by serum) □ Zika virus, IgM antibodies and/or Zika virus, chikungunya virus, dengue virus, PCR Serum in SST, 2mL; CSF, 1 mL; Urine 1 mL; Amniotic fluid 1mL (CSF, urine and amniotic fluid must be accompanied by serum) (requires pre-approval by OSDH Acute Disease Service) 								
Mycobacteriology/Mycology	Parasitolo		, 00011						
 ☐ Fungal isolate, identification Plate or slant with visible growth ☐ Mycobacteria, smear and culture w/ reflex to identification Respiratory sediments, 5-10 mL; Sterile fluid, >2 mL; Blood, 5-10 mL ACD or heparin; Tissue, 1 g; Urine, >5 mL ☐ Mycobacteria, isolate identification Liquid culture, >3 mL; Solid culture, visible growth 	Parasite Babesia/t smears, 1 Malaria:	es, 2 g or Lides, blood trypanosom thick and t	quid feces, 5 nes/filariae: 1 thin Giemsa-Wrig	i-10 mL in F	PVA and 10% Giemsa-Wrig blood smean	ht-stained b			
☐ M. tuberculosis complex PCR Respiratory sediments, 5-10 mL (CHDs require OSDH TB physician pre-approval)	☐ Parasite Impression	•		ntact lab; re	equires pre-a	pproval)			